

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER _____

CORRESPONDENCE

ABBOTT

Hospital Products Division

Abbott Laboratories
Dept. AP30
500 Standish Park Road
North Park, Illinois 60064-3537

December 3, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
North Park North II
500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

Via FAX (and Paper) 301-594-1174

Re: ANDA 75-241 Furosemide Injection, USP, 10 mg/mL, Plastic Syringe

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product. We are responding to a telephone request on December 1, 1997 from Ms. Sandra Middleton, OGD, to Dr. Thomas Willer, Abbott Laboratories. The Agency made the following requests:

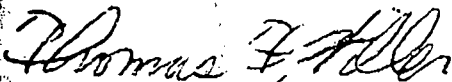
1. Please revise the Form FDA 356h to include drug indication information and innovator firm's name.
2. Please update the application with information pertaining to the plastic syringe data package.

We provide a revised Form FDA 356h with this response. As noted in the cover letter to this original ANDA, dated October 31, 1997, the data package on the plastic has already been submitted as a supplement.

Plastic Syringe, Division Of Metabolism And Endocrine Drug Products, HFD #510. Dr. Stan Koch, FDA chemist, was the primary reviewer. He has finished his review and is awaiting completion of the pre-approval inspection of the CFN occurring in either December, 1997 or January, 1998. We commit to submitting that sNDA approval letter to this ANDA. It will be the first NDA approval of a drug in this plastic syringe.

Sincerely,

ABBOTT LABORATORIES



Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-6845
Fax: (847) 938-7867
Internet: WILLETF@hpd.abbott.com
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9:12-97f.tfw/1

P.2/4

DEC 03 '97 09:52AM D389 REG AFFAIRS (847)938-7867
847 938 7867



Hospital Products Division
Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

October 31, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

RECEIVED

NOV 3 1997

GENERIC DRUGS

RE: Furosemide Injection, USP, 10 mg/mL, in Plastic Syringe

ORIGINAL ABBREVIATED NEW DRUG APPLICATION

Abbott Laboratories hereby submits this original Abbreviated New Drug Application for the subject drug to provide for Furosemide Injection, USP, 10 mg/mL, in plastic syringe, in accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act. The subject drug is an aqueous sterilized drug product. The dosage form and manufacturing site may be described as follows:

The dosage forms and manufacturing sites may be described as follows:

<u>Abbott List Number</u>	<u>Concentration</u>	<u>Fill Volume</u>	<u>Size/ Type Container</u>	<u>Manufacturing Facility</u>
9631	10 mg/mL	4 mL	5 mL Plastic Syringe	F I
1639	10 mg/mL	8 mL	10 mL Plastic Syringe	I I
1639	10 mg/mL	10 mL	10 mL Plastic Syringe	

Abbott Laboratories is filing this ANDA in accordance with guidance furnished by CDER concerning packaging changes for established drug products from glass to plastic primary containers. The Agency has determined that the process for submitting currently approved small volume parenteral products in glass containers to be packaged in plastic containers shall be via an abbreviated new drug application. We submit this application in accordance with MAPP 6020.2, "Applications for Parenteral Products in Plastic Immediate Containers," issued September 6, 1996. This application is submitted in accordance with MAPP 6020.2 in that this product duplicates and approved product listed in the current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* and studies were not required beyond confirmatory testing.



D. Sporn
Page Two
October 31, 1997

The subject drug is a prescription drug and not an over-the-counter drug. Abbott Laboratories' Hospital Products Division will manufacture the finished dosage form at its currently approved Rocky Mount, North Carolina facility (CFN). Please refer to Drug Master File or a full description of this Abbott Laboratories, Hospital Products Division facility.

Please refer to the accompanying Table of Contents for a list of the data supporting this newly prepared submission. These data have been presented in five volumes consistent with the Office of Generic Drugs Policy and Procedure Guide #30-91, entitled "Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application," dated April 10, 1991.

We also include in Section XXI of this application the "Certification Requirement for All Applications For Approval of a Drug Product" and "Certification Requirement for All Applications For Approval of a Drug Product Concerning Using Services of Disbarred Persons" as required by the Generic Drug Enforcement Act of 1992.

In compliance with 21 CFR 314 covering FDA preapproval inspections of manufacturing sites, Abbott Laboratories has submitted a complete true copy of the CMC section from this application ("designated as the field copy") to the FDA district office (Atlanta, Georgia) with inspection responsibilities for the Abbott Laboratories Hospital Products Division manufacturing site (Rocky Mount, North Carolina) listed in this application. The signed certification follows this letter.

We request twenty-four months expiration dating for this product based on the accelerated stability data enclosed herein. At the request of the Agency, we will provide samples of the bulk drug substance and finished dosage form.

This is the seventh in a series of submissions of drug products to be packaged in plastic syringes. These products were summarized in Dr. Williams' letter (September 3, 1996). The first submission was for Plastic Syringe, as a supplement to NDA 5, *Division Of Metabolism And Endocrine Drug Products*, HFD #510. This supplement was accepted for review on May 30, 1996 and the Agency review is being completed now. We have included the *full data package* for the plastic container in that submission. The second submission, ANDA Plastic Syringe, was submitted on November 14, 1996, and included a full (duplicate) data package. These two submissions contain the same data package for the plastic syringe. We request that the previous new drug review division and previous OGD reviews of this documentation cover this submission too. We do not include this information again here.

Additionally, we include after this letter a copy "Checklist For Completeness And Acceptability For Filing Abbreviated Applications." This is part of Mr. Douglas Sporn's letter to industry, April 8, 1994, as Attachment A. We added an extra column the OGD checklist in which we included the location (volume number and page number) in this ANDA where the specified information can be found. We hope that this aid will permit the Agency to expedite its prereview and acceptance of the ANDA.



D. Sporn
Page Three
October 31, 1997

We also note that Abbott Laboratories has extensive experience manufacturing 10 mg/mL Furosemide Injection products. We manufacture many other Furosemide products in large volume containers and small volume containers, including, glass syringes, vials, ampuls, and flexible containers. The present product differs from the above products in that it is a plastic syringe.

We trust that this submission is complete and this abbreviated new drug application can be expeditiously approved. Please contact me if you have any questions or need additional information concerning this submission.

Sincerely,

ABBOTT LABORATORIES

Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-6845
Fax: (847) 938-7867
Internet: WILLETF@hpd.abbott.com

TFW:tw

furo9631.tfw/5
Attachment

ANDA 75-241

Abbott Laboratories
Attention: Thomas F. Willer, Ph.D. /
200 Abbott Park Road D-389 AP30
Abbott Park IL 60064-3537

DEC 10 1997

|||||

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to the telephone conversation dated December 1, 1997 and your correspondence dated December 3, 1997.

NAME OF DRUG: Furosemide Injection USP, 10 mg/mL, in Plastic Syringe

DATE OF APPLICATION: October 31, 1997

DATE (RECEIVED) ACCEPTABLE FOR FILING: November 3, 1997

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Jim Wilson
Project Manager
(301) 827-5848

Sincerely yours,

11/1/57

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc:

Endorsements:

11/1/57

12/9/57



Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

March 5, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

NDA ORIG AMENDMENT

N/A M

ATTENTION: Douglas Sporn
Director

Re: ANDA 75-241 Furosemide Injection, USP
MINOR AMENDMENT

Abbott Laboratories hereby amends the above-referenced abbreviated new drug applications for the subject drug product to provide for packaging the product in a plastic syringe container. We are responding to the Agency's faxed letter dated February 17, 1999, which made the following comments:

COMMENT: "A. Deficiencies:

1. The DMF or Furosemide USP was reviewed and was found to be inadequate. The DMF holder has been notified of the deficiencies. Please do not respond to this deficiency letter until you have received notification that the DMF holder has addressed all of the deficiencies."

RESPONSE: The DMF holder, has informed Abbott Laboratories that they have replied on February 10, 1999 to the FDA deficiency letter dated December 22, 1998. We provide's cover letter that was sent to the Agency on February 10, 1999 in EXHIBIT I.

COMMENT: "2. The statistical review provided on page 22 for Breakloose and Extrusion forces for Plastic Syringes states that except for the breakloose results for pH 3 water, the breakloose and extrusion results changed significantly from interval to interval. Please explain how this variability will impact the functionality of the syringe to deliver the intended volume. In addition, please define the terms "breakloose" and "extrusion forces" as they apply to this study and also define the Syringe system that was being tested."

RESPONSE: The statistical review provided on Page 22 for Breakloose and Extrusion forces of plastic syringe in the major amendment dated July 9, 1998 deals specifically with *statistical* significance; that is, with the probability that the result could or could not have occurred by chance. When small differences are statistically significant, however, this does not necessarily mean that they have any practical impact on the functionality. In fact, these differences are not functionally significant.

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MAR 08 1999

GENERIC DRUGS



Douglas Sporn
Page Two
March 5, 1999

Reviewing the data, one can see that there are no trends toward either higher or lower forces developing over the stability period. The trending patterns do not indicate a relationship between time and results, and the twenty-four month means were not significantly different from the time zero means. All results were within our pre-established acceptance criteria.

As to the definitions of breakloose and extrusion forces, breakloose force is the force required to initiate the movement of the plunger. Extrusion force is the force required to sustain movement of the plunger through the delivering the contents of the syringe.

COMMENT: "3. With respect to the graduation accuracy report (page 39 of this submission), please specify the following (a) the type and make of syringes used in the study (b) How do these results meet the USP requirements for volume of injection in containers? From the data provided, some of the volumes delivered may be less than the labeled amount. (C) This report studied the accuracy of delivery based on label placement, please summarize the delivery of the syringes without reference to the placement of the label. (d) Please provide the test methodology and actual data for this study."

RESPONSE: (a) The syringes used in this study were made of proprietary materials supplied by . They were 5 mL and 10 mL syringes filled with 5 mL or 10 mL water.

(b) The graduation accuracy is a separate issue from USP volume requirements. We ensure having "not less than the labeled volume" of solution in the container governed by appropriate manufacturing controls and confirmed by finished product testing, as noted in previously submitted batch record data.

The report provided on Page 39 of the Amendment dated July 9, 1998 was meant to address the accuracy of delivery using the graduation scale placed on the syringe when partial dose is delivered between two graduation lines, or when a full content is measured after first expelling of the air and overfill. For the entire content of solution syringe, we have fill volume specifications set to "not less than labeled volume" which are in compliance with the USP requirement.

(c) and (d) We provide the summary of the graduation accuracy study results and the methodology with actual data for this study in EXHIBIT II.



Douglas Sporn
Page Three
March 5, 1999

COMMENT: "4. Please revise the specification for the particulate matter test at release and on stability and establish limits for this test. In addition, please indicate the levels of particles that would require an action to occur and explain what is done with this information if the product fails."

RESPONSE: In response to the Agency's question, Abbott Laboratories will test for particulates in this syringe product. However, the prefilled syringes are exempted from the USP particulate testing requirement. The Abbott Standard Test Method provides testing criteria consistent with USP limits shown on page 13 of the document. The test method describes action to be taken in case of failures. We have previously provided this Standard Test Method, P-n Page 78 - 93 in the Amendment dated July 9, 1998.

COMMENT: "5. Your references to the approved extractables testing for NDA and ANDA are acknowledged. Please explain how this study relates to extractables for this product. Although the container closure system has been previously approved, there is no information provided to this application regarding extractables with this drug product's vehicle. Please provide this information to the application."

RESPONSE: During development of testing for the plastic syringes, Mr. Stanley Koch, Surgical and Dental Products Division of FDA, reviewed a proposal to use of family of solutions to cover ten variety of drug products. We have conducted an extractables study to monitor for the potential extractables and in a family of solutions consisting of Water for Injection, pH 6 and Water for Injection, pH 9.5. The test period covered two years. This comprehensive study provided the basis for nine other drug products packaged in the syringe in 1998.

The Furosemide Injection would be bracketed by the above family of solutions. For example, the pH range of Furosemide product is bracketed by the above Water for Injection, pH 6 and Water for Injection, pH 9.5 solutions. Similarly, the organic content of the Furosemide Injection is bracketed by the and the several Water for Injection solutions.

This same bracketing concept has received OGD approval as part of several other ANDA submissions in the same plastic/rubber syringe packaging system, including Iopamidol Injection (ANDA and injection



Douglas Sporn
Page Four
March 5, 1999

COMMENT: "6. Please revise the stability protocol to specify that the first three lots of each fill/strength of each container closure system will be placed on stability and annually thereafter, one lot of each strength/fill in each container closure system will also be placed on stability. In addition, please specify that the expiration date for the product may be extended with the supporting data from three consecutive lots of each strength/fill of product in each container/closure system."

RESPONSE: We have changed the marketed product stability protocols per Agency's request. The revised protocols are provided in EXHIBIT III.

COMMENT: "In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response.

1. Your reference to ANDA listed in the response to comment 12 of the July 9, 1998 amendment is not correct. Please provide a correct reference."

RESPONSE: The correct reference should be ANDA, Section. We regret any inconvenience due to this typographical error.

COMMENT: "Labeling Deficiencies:

1. CONTAINER - 4 mL, 1 mL, & 10 mL Single-dose Syringe.
Satisfactory in FPL as of July 9, 1998 submission.
2. CARTON - 4 mL, 1 mL, & 10 mL
Revise the net quantity statement to read "____ mL Syringe"
3. INSERT
Satisfactory in FPL as of July 9, 1999 submission."

RESPONSE: The net quantity statement shown on the carton final printed labeling only states the volume description for 4 mL, 1 mL and 10 mL syringes. The word "Syringe" is shown on the front carton panel. Additionally, a picture of the syringe is presented on the back panel. If the word "Syringe" has to be incorporated in the net quantity statement on the same line, due to space constraint, we will have to decrease the size and prominence of the volume description (4 mL, 1 mL and 10 mL).

Per phone conversation on February 23, 1999 between Mr. Charlie Hoppes, OGD, and Dr. Jessie Lee, Abbott Laboratories, Mr. Hoppes agreed that the container description ("Syringe") is already elsewhere on the carton label and is acceptable. He stated that carton final printed labeling provided in the amendment dated July 9, 1998 is satisfactory. Therefore, no revisions are necessary to the carton labeling.



Douglas Sporn
Page Five
March 5, 1999

We trust that this submission is complete and that the ANDA may now be approved. Please telephone me if I may be of further service.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: leej@hpd.abbott.com

JYL:jl

g:3-99fda.jyl/5
Attachment



Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

ORIG AMENDMENT

N/AC

July 9, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

Re: ANDA 75-241 Furosemide Injection, USP
MAJOR AMENDMENT

Abbott Laboratories hereby amends the above-referenced abbreviated new drug applications for the subject drug product to provide for the subject drug product in a plastic syringe container. We are responding to the Agency's letter dated June 9, 1998, which made the following comments:

COMMENT: "A. Deficiencies:

Page(s) 9

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

7/9/98



D. Sporn
Page Eleven
July 9, 1998

COMMENT:

"Labeling Deficiencies:

1. **CONTAINER - 4 mL, , & 10 mL Ansyr single-dose Syringe**
Include the statement "Discard unused portion."
2. **CARTON - 4 mL, , & 10 mL**
 - a. Revise the net quantity statement to read "x mL Single-dose Syringe" and delete the statement "Single-dose unit" on the side panel.
 - b. Increase the prominence of the statement "For I.V or I.M. use". We encourage you to relocate this statement to the main panel.
 - c. we encourage the inclusion of the statement "Contains no preservative." as the last sentence in the text "Each mL ...".
 - d. We note that your trademark "Ansyr™" is more prominent than the established name of your drug products. We ask you to reduce the prominence of the trademark "Ansyr™"
3. **INSERT**
 - a. **DESCRIPTION**
 - i. We encourage you to relocate the RAO numbers and revision date to follow the HOW SUPPLIED section.
 - ii. First paragraph
We encourage the inclusion of the statement "Contains no preservative." as the last sentence.
 - iii. Revise the molecular weight to read "330.75" to be in accordance with USP 23.
 - b. **CLINICAL PHARMACOLOGY**
It is preferable to use "mcg" rather than "µg" when referring to micrograms.
 - c. **PRECAUTIONS (Carcinogenesis, Mutagenesis, Impairment of Fertility)**
Delete the last paragraph.
 - d. **OVERDOSAGE - third paragraphs:**
 - i. Relocate the second sentence to begin as a new paragraph.
 - ii. Relocate the last sentence to begin as a new last paragraph.
 - e. **HOW SUPPLIED**
 - i. Include "Discard unused portion."
 - ii. We encourage the inclusion of the statement "Do not remove from carton until ready for use."

Please revise your container labels and carton and package insert labeling, as instructed above, and submit in final print."

RESPONSE: We revised the labeling as requested and attach twelve copies of final printed labeling. Please see Exhibit XVII.

COMMENT: "The Division of Bioequivalence has completed its review and has no further questions at this time."

RESPONSE: No response required.



D. Sporn
Page Twelve
July 9, 1998

We trust that this submission is complete and that the ANDA may now be approved. Please telephone me if I may be of further service.

Sincerely,

ABBOTT LABORATORIES

Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-6845
Fax: (847) 938-7867
Internet: WILLETF@hpd.abbott.com

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g:7-98f.tfw/13
Attachment

ABBOTT

Willet
12/9/97

Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

December 3, 1997

NEW CORRESP

NC

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

Via FAX (and Paper) 301-594-1174

Re: ANDA 75-241 Furosemide Injection, USP, 10 mg/mL, Plastic Syringe

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product. We are responding to a telephone request on December 1, 1997 from Ms. Sandra Middleton, OGD, to Dr. Thomas Willer, Abbott Laboratories. The Agency made the following requests:

1. Please revise the Form FDA 356h to include drug indication information and innovator firm's name.
2. Please update the application with information pertaining to the plastic syringe data package.

We provide a revised Form FDA 356h with this response. As noted in the cover letter to this original ANDA, dated October 31, 1997, the data package on the plastic has already been submitted as a supplement to Furosemide Injection, USP, 50 mL, Plastic Syringe, Division Of Metabolism And Endocrine Drug Products, HFD #510. Dr. Stan Koch, FDA chemist, was the primary reviewer. He has finished his review and is awaiting completion of the pre-approval inspection of the Rocky Mount, North Carolina (CFN occurring in either December, 1997 or January, 1998. We commit to submitting that sNDA approval letter to this ANDA. It will be the first NDA approval of a drug in this plastic syringe.

Sincerely,

ABBOTT LABORATORIES

Thomas F. Willer

Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-6845
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g:12-97f.tfw/1

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DEC 08 1997

GENERIC DRUGS



Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

April 14, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

TELEPHONE AMENDMENT

VIA FAX (301) 594-0180

Re: ANDA 75-241 Furosemide Injection, USP

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product to provide for packaging the product in a plastic syringe container. This letter is in response to a phone conversation held between Dr. Vilayat Sayeed of OGD, FDA, and Dr. Jessie Lee of Abbott Laboratories on April 14, 1999 requesting additional information.

The Agency was inquiring of the temperature range used for the storage of the stability samples and the specification for physical appearance test in the stability study. The temperature range is specified at As to the physical appearance test, the specification is

We trust that this submission is complete. We believe that this submission can now be expeditiously approved. Please contact me if I can provide any additional information concerning this submission.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

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MAY 11 1999
CENTRAL

ABBOTT

Hospital Products Division

Abbott Laboratories

D-389, Bldg. AP30

200 Abbott Park Road

Abbott Park, Illinois 60064-3537

May 14, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630

Metro Park North II

7500 Standish Place, Room 150

Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

~~ANDA ORIGIN AMENDMENT~~

N/A/M

Re: ANDA 75-241 Furosemide Injection, USP

VIA FAX (301) 594-0180

TELEPHONE AMENDMENT

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product to provide for the subject drug product in a plastic syringe container. This letter is in response to phone conversations held between Dr. Alan Rudman of FDA, Office of Generic Drugs (OGD), and Dr. Jessie Lee of Abbott Laboratories on May 12 and May 13, 1999.

1. Withdrawal of Fill in 10 mL Size:

Dr. Rudman noted that Abbott Laboratories has bracketed the size using the 5 mL and 10 mL sizes in the stability studies. The OGD requires prior-approved protocol for conducting the stability bracketing. Due to the lack of prior-approved bracketing stability protocol, per Agency's request, Abbott Laboratories hereby withdraws the size for the above-referenced drug product without prejudice to refiling at a later date with all appropriate information. We also withdraw all appropriate documents related to the mL fill size, such as, blank batch record, container-closure system, labeling, final product specifications.

2. Total Impurities Specification Limit for Furosemide Injection, USP:



2
D. Sporn
Page Two
May 14, 1999

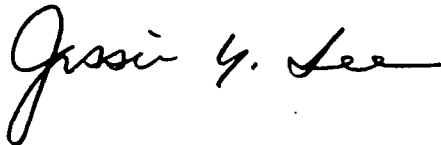
3. Labeling:

Consistent with the withdrawal of the . syringe, we deleted the iL size from the HOW SUPPLY section as requested by the OGD. Abbott Laboratories tries to standardize the presentation of information in all NDA and ANDA drug inserts, and has decided not to include the "Rx only" statement in the Title section when the statement is already shown on the container and carton labels of the drug product. This is permitted per the FDAMA 1997, Section 126, Revised, July 1998. Therefore, the "Rx Only" symbol is deleted in the enclosure labeling. The labeling is provided in Exhibit IV. It is a plate proof. The final printed labeling will be forwarded to the Agency as soon as they are available.

We trust that this submission is complete and this submission can be expeditiously approved. Please telephone me if I can provide any more information.

Sincerely,

ABBOTT LABORATORIES



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

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